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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/085,555   | 02/27/2002  | Shokyu Gen           | F-7323                | 9841             |
| 28107  | 7590        | 04/25/2005           | EXAMINER              |                  |
| JORDAN AND HAMBURG LLP<br>122 EAST 42ND STREET<br>SUITE 4000<br>NEW YORK, NY 10168 |             |                      | HEARD, THOMAS SWEENEY |                  |
|  |             | ART UNIT             | PAPER NUMBER          |                  |
|  |             | 1654                 |                       |                  |

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                            |                     |  |
|------------------------------|----------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>     | <b>Applicant(s)</b> |  |
|                              | 10/085,555                 | GEN, SHOKYU         |  |
|                              | Examiner<br>Thomas S Heard | Art Unit<br>1654    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 March 2005.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 16-18 and 28-36 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 16-18, 28-36 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_



Applicant's election without traverse of endothelial blood vessel cells in the reply filed on March 7<sup>th</sup>, 1005 is acknowledged. It is noted that the elected species, endothelial cells, is drawn to claims that have been cancelled by the applicant.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-36 provisionally rejected under the judicially created doctrine of double patenting over claim 5 of copending Application No. 09/571,960, Pub. No.: US 2002/0164795 A1. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: in the instant application, applicants are claiming a method of forming a protein-polyphenol by addition

polyphenolic compounds to proteins which encompasses claim 5 of the co-pending application. Though formation of a protein-complex is not explicitly stated in the claim, given the inherent nature of polyphenols to adhere to and form complexes with macromolecular molecules (see Yang et al below) one would be forming polyphenol/protein complexes no matter what the reason for combining the two compounds.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-18, and 28, 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by:

Chai Salon, <http://www.chaisalon.com/Recipes/recipes.htm>

and evidenced by Yang et al "The Chemistry of Tea,

<http://www.teatalk.com/science/chemistry.htm>;

Nemours Foundation for Kids Health for Parents "Milk Allergy,

[http://kidshealth.org/parent/medical/allergies/milk\\_allergy.html](http://kidshealth.org/parent/medical/allergies/milk_allergy.html);

and National Cancer Institute "Prevention Agents,"

[http://www3.cancer.gov/prevention/agents/Tea\\_Polyphenols.html](http://www3.cancer.gov/prevention/agents/Tea_Polyphenols.html)

The Chai Salon discloses a method of forming a complex of polyphenols with proteins by extracting out the polyphenols from tea leaves with boiling water and then forming the protein complex by adding milk; see the recipe for Plain Chai on the recipe web address above. Yang et al discloses that polyphenols in tea, comprising a variety of epigallocatechin gallate, tannic acids, flavanols, and variety of flavandiols, flavonoids, and phenolic acids, have a high complex affinity to metals, alkaloids, and biological macromolecules such as lipids, carbohydrates, proteins, and nucleic acids. The affinity of polyphenols for macromolecules is an **intrinsic property** of polyphenols and is not limited to just the compounds in free solution and can bind proteins on the surface of cells. Proteins, lipids, and glycoproteins on the surface of cellular membrane are also capable of complexing with polyphenols, and the elected species of endothelial cells of blood vessels in the instant application are no exception. Additionally, the National Cancer Institute teaches that polyphenols in tea are antioxidants and the Nemours Foundation teaches that milk contains allergens and these milk allergens are animal proteins. Therefore, Chai Salon as evidenced by Yang, National Cancer Institute and Nemours Foundation, anticipate the claimed invention.

Claims 16-18 and 30-35 are rejected as being anticipated by Lehmberg et al, U.S. Patent 5,952,023. Lehmberg et al discloses a process of adding proteins (cell wall digesting enzymes) to slurry of tealeaves in the preparation of tea, which extracts out epigallocatechin, flavonoids, and tannic acids, all which are antioxidants. Lehmberg et al further discloses that the extraction process takes place from 20 minutes to 5 hours

and where the solution is dried (lyophilized/freeze-dried), see claims 1-9 and entire document). Therefore, Lehmberg et al anticipates the claimed invention.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rita V. Copelman, Leather and Hides.

[http://members.aol.com/\\_ht\\_a/centralprr/fazio/page9a.htm](http://members.aol.com/_ht_a/centralprr/fazio/page9a.htm), and de Lathauwer U.S. Patent 6,24,770.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 29, 31 and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al and Chai Salon. Chai Salon teaches a method and product of making a cup of Chai wherein polyphenols are extracted during the incubation of tealeaves with hot water and then adding the protein from animal milk. Although Yang does not teach the various ratios of 15 – 1000, and different form of milk can be used, such as whole, half, and skim, which would change the amount of milk proteins added, it would be obvious to one skilled in the art at the time of invention to determine all operable and optimum component ratios in the claimed composition because the component ratios are an art-recognized result-effective variable that is routinely determined and optimized

in the beverage arts. One would have been motivated to optimize to personal preference of taste. Thus, the invention as a whole would have been *prima facia* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TSH



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